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10/571,504	03/05/2007	Atsuko Fukui	MATOB1.001APC	4157

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/571,504	FUKUI, ATSUKO	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☒ Claim(s) *4-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 4 – 11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4 – 11 are not been further treated on the merits.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1 and 3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5 of copending Application No. 12/682747. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 3 of the instant application are generic to all that is recited in claims 1 and 5 US Application 12/682747. That is, claims 1 and 5 of US'747 falls entirely within the scope of claims 1 and 3 or, in other words, claims 1 and 3 are anticipated by claims 1 and 5 of US'747. Specifically, the claims of both applications recite granular jelly beverages comprising 0.1 – 15% of a bitterness masking component including a vegetable fat and oil and/or an animal fat and oil; 5 – 20% bitterness masking supplemental component including a sugar alcohol; 0.1 – 5% of least one gelatinizing compound selected from the group consisting of

carrageenan, gellan gum, locust bean gum, xanthan gum, guar gum and pectin; water and optionally an ingredient selected from the group consisting of sucrose fatty acid ester, glycerine fatty acid ester, sorbitan fatty acid ester, propylene glycol and propylene glycol fatty acid ester (instant claim 3; claim 5 of US'747). In addition, the compositions of US'747 also require the presence of 0.1 – 5% of at least one type of taste adjusting ingredient.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 – 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of claim 1 requires that the drink be "granular". This limitation has not been defined by Applicant and a review of the specification and examples contained therein does not define what is meant by this term. Granular would seem to indicated that distinct smaller pieces that make up the whole are present in the final product but in the looking at the examples, no mention is made of a step or process that would produce something other than a product that appears homogenous on the macroscopic level. Granules or fine granules can be

added to the preparation (p 5, ¶ 5) but if the drink is not granular until the addition of such elements, then essential elements are missing from claim 1. Alternatively, "granular" could mean that granules of the non-water ingredients are formed and then hydrated with water to form a drink but that the drink itself does not appear granular.

Different parts of the preamble of claim 1 require a "jelly drink" (line 1) or "jellylike beverage" (line 3). Applicants have not defined what is meant by "jellylike" as opposed to a jelly and even if such a definition had been provided, it is unclear whether the composition must be a jelly or merely jellylike.

The element(s) required for the "bitterness masking component" is unclear. It is unclear if only one of the elements from the list of vegetable fat, vegetable oil, animal fat and animal oil need be present or if both a fat and oil from the same source (vegetable or animal) must be present in order for this limitation to be met.

These rest of the claims fall therewith. Please clarify.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagami et al. (WO 00/54811; all citations from US 2005/0152975, a continuation of the PCT application) in view of Fukui et al. (US 6,277,395).

Nakagami et al. discloses granular pharmaceutical compositions that mask the disagreeable taste of the drug and provides a favorable sensation upon oral administration (¶ [0001]). The addition of a sugar alcohol to the drug and wax substance provides a formulation with excellent ability to mask the taste and provide a favorable sensation (¶ [0007]). The waxes that can be used are hydrogenated oils such as the vegetable oils soybean and rape seed; fats and oils of vegetable or animal origin; fatty acids and derivatives such as fatty acid glycerin esters and fatty acid sucrose esters and mixtures of two or more of these substances (¶ [0054]). These waxes read on the bitterness masking component of the instant claims. The wax is melted and the drug is dissolved or dispersed therein (¶ [0057]). The sugar alcohol in the mixture is at least 10 wt% (¶ [0056]). Powder granules comprising about 62% wax (tri-fatty acid glycerin ester) were prepared in example 5 (¶ [0075]) and then dissolved in water in test example 7 (¶ [0080]). In that formulation the concentration of the wax was about 1%.

Nakagami et al. does not disclose jelly drink containing at least one gelatinizing component from the Markush group recited in claim 1.

Fukui et al. discloses swallowing assistive drinks made using water and an adhesive paste that provides viscosity to the water upon mixing (col 3, ln 24 – 32). Patients can have difficulty swallowing, can choke or not take the full dose of medicine when it is administered in forms such as powders (col 1, ln 17 – 21). The swallowing assistive drink improves the swallowing of various medicines while remaining convenient for use because of the use of ordinary water to prepare (col 1, ln 47 – 53). The granules are readily swallowed and do not stick in the mouth because they are enwrapped by the drink (col 4, ln 35 – 43). Agar, carrageenan, gellan gum, furcellan, gelatin, locust bean gum, guar gum, xanthan gum, arginic acid, psyllium seed gum or tamarind gum (col 3, ln 32 – 39). 8-10 wt % sugars including the sugar alcohols mannitol and erythritol can be included in the drink (col 4, ln 1). Various jellied drinks are prepared in the examples and they generally contain about 8.8 wt % sugar alcohol (mannitol or erythritol) and between 0.32 % and 2 wt % total of gelatinizing agents (the formulations use more than one such agent).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the taste masked granules of Nakagami et al. to prepare a jellied drink as taught by Fukui et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Fukui et al. disclose that people can have difficulty swallowing the full doe of granular medicine and by adding gelatinizing agent and mixing with water, a

drink prepared from granules that allows for swallowing the full dose. Nakagami et al. discloses that vegetable or animal fats and oils can be used as the wax ingredient to provide taste masking to bitter active ingredients, that could cause such a drink to have an unpleasant taste.

The "granular" limitation recited in the preamble is met because granular materials are added to the water to prepare the drink. This is the same process disclosed in the examples of the instant application that lead to the preparation of a bitterness masking granular jelly (e.g., example 1, p 19).

The amount of wax (bitterness masking component) present in the drink formulations of Nakagami et al. fall within the range recited by Applicant. The use of such granules with the thickeners and higher amounts of sugar alcohols will sweeten and provide nutrition in the formulations of Fukui et al. also lie within the ranges disclosed recited in claim 1. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, based on the taste to be masked, the desired dose and the desired sweetness of the final jelly beverage.

9. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagami et al. and Fukui et al. as applied to claim 1 above, and further in view of Sugao et al. (J Pharm Sci, 1998).

As discussed in greater detail above, Nakagami et al. and Fukui et al. discloses granular jelly beverage for easily taking full doses of powdered medicine for patients with difficulty swallowing that comprises a wax to mask the flavor, at least one sugar alcohol and at least one gelatinizing agent. Nakagami et al. discloses that hydrogenated oils such as the vegetable oils soybean and rape seed; fats and oils of vegetable or animal origin; fatty acids and derivatives such as fatty acid glycerin esters and fatty acid sucrose esters and mixtures of two or more of these substances can be used as the taste masking wax.

Nakagami et al. does not explicitly described the use of a combination of vegetable or animal fat and oil with one of the hydrofuge inhibition components in the Markush group of claim 3 such as fatty acid glycerin esters and fatty acid sucrose esters.

Sugao et al. discloses taste masking of an unpleasant drug powder with a mixture of hydrogenated oil and sucrose fatty acid ester (p 96, col 1, ¶ 3; Table 1, p 97). The addition of the sucrose fatty acid ester (formulation C uses hydrogenate oil only) to the taste masking coating results in faster dissolution (p 98, table 4). The Lubri wax 103 oil used by Sugao et al. is a hydrogenated rape seed oil (col 2, ln 42 – 46 of US 5,290,569).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use a combination of a vegetable oil and sucrose fatty acid ester to taste mask the drug particles in order to provide for a faster dissolution of the granules after ingestion. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success as Nakagami et al. discloses that combinations of materials can be used to taste mask and Sugao et al. discloses that the composition of the taste masking composition alters the dissolution profile of the drug and that this particular combination increases the dissolution rate of the drug, leading to a more rapid onset of the pharmacological action.

10. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagami et al. and Fukui et al. as applied to claim 1 above, and further in view of Nakamura et al. (WO 01/66083; all citations from machine translation).

As discussed in greater detail above, Nakagami et al. and Fukui et al. discloses granular jelly beverage for easily taking full doses of powdered medicine for patients with difficulty swallowing that comprises a wax to mask the flavor, at least one sugar alcohol and at least one gelatinizing agent. Nakagami et al. disclose that substances to adjust the pH can be included in the compositions (¶ [0063]).

A specific pH range for the composition is not disclosed.

Nakamura et al. discloses oral gel preparations (p 1, "technical field") that contain carrageenan, a sugar alcohol and sorbic acid (claim 1). The pH of the preparation must

be between 4 – 9 with range of 4 – 7 and 5 – 6 being more preferred to provided suitable stability to the gel ((p 3, ln 1 – 2).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare a granular jelly drink having a pH of 4 – 9 or even between 5 and 6. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Nakamura et al. disclose that such a pH range is suitable to provide gel stability for carrageenan and sugar alcohol gels which are oral administrable. The optimal pH may also vary depending on the particular gelatinizing agent(s) used and the stability of the drug being administered in the composition.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa M Westerberg/
Examiner, Art Unit 1618